Office of General Counsel

Nelson E. Schmidt

Associate Counsel

November 2, 1987



Nelson Leidel Docket Officer National Institute for Occupational Safety and Health Mail Stop D-371600 Clifton Road N.E. Atlanta, GA 30333

Re: Proposed Rulemaking for Certification of Respirators, 42 CFR Part 84

Dear Mr. Leidel:

In response to the notice published by the Secretary of Health and Human Services on Thursday, August 27, 1987 (52 Fed Reg 32402 et seq) setting forth proposed regulations for the certification of respirators in 42 CFR Part 84, 3M submitted a letter dated September 8, 1987 directed to the attention of Mr. John Moran requesting the following:

- 1. An extension of the comment period from October 26, 1987 to April 26, 1988;
- 2. A recall of the entire proposal until field test protocols are issued; and
- 3. Public hearings to present testimony and question presentors. (A copy of the September 8 letter is enclosed for your convenience and reference)

Subsequently, I received a phone call from Mr. Moran and was told that the comment period would be extended and that public hearings would be conducted. He did not have an answer to the request that the proposal be withdrawn, but told me I would be receiving a formal answer to this issue as well as the others raised in my September 8 letter. While no written reply has thus far been received, I am sure the shift in responsibility for this proposed rule from Mr. Moran to yourself has caused some delays or miscommunications in responding.

Minnesota Mining and Manufacturing Company

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Rec'd 117/87

Nelson Leidel Page Two November 2, 1987

Nevertheless, and notwithstanding the Federal Register notice on October 8, 1987 (52 Fed Reg 37639) extending the comment period from October 26 to December 28, 1987 and establishing public meetings in January, 1988, I still solicit your timely response setting forth the Secretary's position on the issues previously raised.

Finally, 3M takes issue with the Secretary's determination that in accordance with Executive Order 12291, this proposed rule would have an annual effect on the economy of less than \$100,000,000 (52 Fed Reg 32404). Using NIOSH's draft for measuring workplace protection factors contained in a May 27, 1987 document entitled "Experimental Design in Research Protocol to Assign Protection Factors for Negative Pressure Respirators", 3M estimates that field testing its current product line would cost more than \$136,000,000 and would be over \$200,000,000 if products planned for introduction during the next year are included. Moreover, the time involved for this testing would require approximately 950 man years. Thus, for 3M alone compliance with the proposed certification rules would have an annual economic impact far in excess of \$100,000,000. Based on the magnitude of error on this point, 3M submits that the Secretary also reconsider its determinations on the other categories addressed in the Federal Register regarding Executive Order 12291.

For the reasons stated above, 3M renews its request that the proposed rule for certifying respirators contained in 42 CFR Part 84 be withdrawn until the short comings of that proposal are corrected and field test protocols are promulgated. Because time is of the essence with respect to these matters your prompt attention and response would be greatly appreciated. Should you have any questions regarding the matters discussed herein, please contact the undersigned at your convenience. Thank you.

Very truly yours,

Melmu E. See

Nelson E. Schmidt

NES: jmd

Enclosure